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AKIN GUMP STRAUSS HAUER & FELD LLP
22ND FLOOR ONE COMMERCE SQUARE
2005 MARKET STREET
PHILADELPHIA PA 19103

EXAMINER

PHAN, H

ART UNIT

PAPER NUMBER

3738

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/079,618

Applicant(s)

Grundel et al.

Examiner

Hieu Phan

Group Art Unit

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☒ Responsive to communication(s) filed on Oct 18, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-8 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrey et al.(U.S. Patent 4,608,055) in view of Caldalise et al.(U.S. Patent 5,897,592) and further in view of Gradinger et al.(U.S. Patent 5,433,750).

3. Morrey et al. disclosed an artificial hip joint with the following features: 1) adapted to be implanted in only the neck of the femur, comprising a shell implanted in the upper region of the femur but below the greater trochanter without using cement(column 7 lines 29-35) 2) the proximal end of the shell is able to connect with an artificial spherical joint part(figure 1) 3) the distal end of the shell have a caudal shape(figure 1) 4) the exterior of the shell is partially covered with a fibrous metal pad(column 5 lines 18-30) 5) the femoral component have a basilar neck portion 15 connected to the neck portion 13(column 5 lines 62-68 and figure 1) 6) the stem portion 50 is formed with a conical taper from its proximal portion 51 up to the beginning of the bend of the stem portion(figure 1). Regarding claims 1, 3, 4, 6 and 8, Morrey et al. failed to mention the artificial hip joint having the following features: 1) the distal portion 53 is partially covered with a fibrous metal pad 2) the fibrous metal is formed on the shell exterior

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sides in caudal and cranial directions with a width of about 2-6 mm 3) the fibrous metal is formed on the shell exterior sides in ventral and dorsal directions with a width of about 1-2.5 mm 4) the fibrous metal is formed on the proximal face 31 of the basilar neck portion 5) a method of implanting a femur endoprosthesis for an artificial hip joint.

4. Caldalise et al. disclosed a prosthesis with some macro-textured surface regions that partially cover the exterior surface and the distal end of the prosthesis (figure 1). The macro-textured surface regions are located at the distal end in order to promote tissue ingrowth and improve fixation of the prosthesis within the body.

5. Gradingner et al. disclosed an artificial hip joint with an open-mesh three-dimensional structure at least partly covering its surface (figure 1). The mesh covering the prosthesis has different diameter sizes ranging from 1.5-6mm (column 2 lines 32-37). The surface of a prosthesis is divided into three zones A, B and C (figure 1). The largest mesh size of the surface structure is in zone A; in zone B a medium mesh size; and finally in zone C the smallest mesh size. The purpose of the distinct zones is to promote cells with different sizes to grow.

5. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teachings of Caldalise et al. and Gradingner et al. to modify the artificial hip joint of Morrey et al. to have the following features: 1) the open-mesh three-dimensional structure partly covering the distal end of the prosthesis would improve the fixation of the artificial joint to the femur 2) the surface sides facing in the caudal and cranial directions are covered with a mesh that has a width ranging from about 2-6mm and the surface sides facing

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in the ventral and dorsal directions are covered with a mesh that has a width ranging from about 1-2.5mm would promote cells with different sizes to grow on the mesh and firmly securing the artificial joint to the femur. It would have been obvious matter of design choice to modify the femoral component of Morrey et al. to have an open-mesh three-dimensional structure partially covering the proximal face 31 of the basilar neck portion, since applicant has not disclosed that having the mesh partially covering the proximal face of the basilar neck portion solves any problem or is for any particular purpose and it appears that the prosthesis would perform equally well without the mesh partially covering the proximal face of the basilar neck portion. Also, claim 1 is rejected because it would have been obvious to one having ordinary skill in the art, since the steps of implanting the shell, the proximal end being connect able with an adapter for accommodating an artificial spherical joint part and positioning the shell are conventional in the art and is dictated by the structure of the femoral prosthesis..

4. Claims 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrey et al.(U.S. Patent 4,608,055) in view Caldarise et al.(U.S. Patent 5,897,592), Gradinger et al.(U.S. Patent 5,433,750) and further in view of Calderale et al.(EP 579 868 A2).

Morrey et al., Caldarise et al. and Gradinger et al. are explained as before. Regarding claim 7, Morrey et al. further lacks the shell being continuously bent throughout a distal portion and the stem end including a concave section a portion of which is adapted to be generally aligned with the longitudinal axis of the femur bone.

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Calderale et al. disclosed a femoral rod with a distal portion (16) having a curved axis and axial grooves (22) for increasing flexibility(column 3 lines 38-40 and 50-58).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teachings of Caldalise et al., Grading et al. Calderale et al. and to modify the artificial hip joint of Morrey et al. to have the shell being continuously bent throughout a distal portion and the stem end including a concave section a portion of which is adapted to be generally aligned with the longitudinal axis of the femur bone. The motivations for incorporating the features of Caldalise et al., Grading et al. Calderale et al. into the apparatus of Morrey et al. are the curved distal portion (16) and axial grooves distribute and absorb the force cause by the patient's movement. It would have been obvious to one having ordinary skill in the art at the time the invention was made to increase or decrease the number of axial grooves depending on the desire stiffness of the distal portion (16).

Response to Arguments

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Applicant's arguments filed on 10/18/1999 have been fully considered but they are not persuasive. In the U.S. Patent 4,608,055, figure 5, the bend is three-fourth from the tip therefore the bend would be consider near the tail region.

Applicant argue that it was improper to combine Caldarise et al., Gradinger et al. and Morrey et al. to produce the Applicant's hip joint. In the amended claims 1 and 7, "adapted to be implanted in only the neck of the femur," is a broad limitation. The limitation does not clearly or distinctly point out the boundaries of the neck of the femur bone where the prosthesis is implanted. Due to the broad claim language of claims 1 and 7 the combination Caldarise et al., Gradinger et al. and Morrey et al. to produce the Applicant's hip joint is proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hieu Phan whose telephone number is (703) 308-8969. The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 6:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached at (703) 308-2672. The fax phone number for this group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceedings should be directed to the group receptionist whose telephone number is (703) 308-0858.



Hieu Phan



Michael J. Milano
Primary Examiner
TC 3300, AU 3308